K060892

APR 14 2006

510(k) Summary
for
Sirona Dental Systems
GALILEOS

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94

Date Prepared: March 17, 2005

2. DEVICE NAME

Proprietary Name:	GALILEOS
Common/Usual Name:	System, X-Ray, Extraoral, Digital
Classification Names:	Extraoral source x-ray system

3. PREDICATE DEVICE

Hitachi CB Mercuray Dental Cone Beam X-Ray System (K033248)

4. INTENDED USE

GALILEOS consists of an x-ray device that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume-reconstructions of the head area, which includes ENT and dentomaxillofacial areas, for use in planning and diagnostic support.

GALILEOS comprises a package of PC software modules to expand SIDEXIS capabilities to handling 3D data. This includes 3D reconstruction, storage, retrieval, viewing and processing of 3D-image data.

5. DEVICE DESCRIPTION

The GALILEOS comprises of the GALILEOS-device, the reconstruction server and the 2D and 3D viewing client SIDEXIS. The GALILEOS device generates a conical x-ray beam that rotates round the patient's head within a certain angle. From the obtained exposures a three dimensional image is reconstructed and can be viewed. The GALILEOS features the navigation within this displayed volume and special views may be selected, calculated and eventually displayed.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The GALILEOS is substantially equivalent to the Hitachi CB Mercuray Dental Cone Beam X-Ray System (K033248) based on the equivalence of the intended use, similar features and technical characteristics. Performance testing to validate the safety and effectiveness of the GALILEOS included electrical safety, electromagnetic compatibility, and validation testing of both hardware and software functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 14 2006

Sirona Dental Systems GmbH
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K060892
Trade/Device Name: GALILEOS
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: March 31, 2006
Received: April 3, 2006

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K060892

Device Name: GALILEOS

Indications for Use:

GALILEOS consists of an x-ray device that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume reconstructions of the head area, which includes ENT and dentomaxillofacial areas, for use in planning and diagnostic support.

GALILEOS comprises a package of PC software modules to expand SIDEXIS capabilities to handling 3D data. This includes 3D reconstruction, storage, retrieval, viewing and processing of 3D-image data.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060892